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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,745	03/15/2001	Howard L. Weiner	B0801/7202 (AWS)	5345

7590

07/23/2003

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EXAMINER

LIU, SAMUEL W

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 07/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/809,745

Applicant(s)

WEINER ET AL.

Examiner

Samuel W Liu

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2001 (Paper No. 5).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11, 19, 25, 31 and 44 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-11, 19, 25, 31 and 44 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

### DETAILED ACTION

Preliminary amendment filed 29 November 2001 (Paper No. 5) prior to patent examination as to cancellation of Claims 12-18, 20-24, 26-30, 32-43 and 45-55, and amendment of claims 1-11, 19, 25, 31 and 44 have been entered. Thus, Claims 1-11, 19, 25, 31 and 44 are pending and the following is applicable to the pending claims.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, 19 and 31, drawn to a method of treating a mammal having a vascular disorder in which a cell-mediated immune response involves comprising administering to said mammal a composition comprising a heat shock protein, are classified in class 514, subclass 2, class 424, subclasses 93.21 and 40, class 530, subclasses 350, and class 435, subclass 7.1.
- II. Claim 25, drawn to a method of suppressing a cell-mediated inflammatory disorder in a mammal comprising administering to said mammal a composition comprising a heat shock protein, are classified in 514, subclass 2, class 424, subclasses 130.1 and 93.21, and, class 530, subclasses 350 and 387.1.
- III. Claims 44, drawn to a composition comprising heat shock protein, are classified in class 530, subclass 350<sup>+</sup>, and class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Invention III is related to I and II as product and alternative processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Groups I and II demonstrate alternative methods of use.

Inventions I and II are related as different and/or distinct methods, a method of treating a vascular disorder and a method of suppressing a cell-mediated inflammatory disorder. These two

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methods differ with respect to pathological mechanism, method steps, clinical outcome, targets, ingredients; therefore, each method is patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification, art recognized divergent subject matter, separate search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

swl

Samuel W. Lin, Ph.D.

July 12, 2003

  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER